Remarks

Claims 1-3, and 6-46 are pending. Claims 19-33 and 35-46 were previously withdrawn. Claims 1-3, 6-18 and 34 are rejected. Claims 4-5 are canceled.

Rejections under 35 U.S.C. 112, first paragraph

Claims 1-3, 6-18 and 34 are rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement for failing to specify how the anti-thrombogenic material is immobilized within the base coat layer. Applicants believe the amendment to claims 1, 15 and 34 cure this deficiency.

Claims 1-3, 6-18 and 34 are rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement because the title of the present invention includes polyurethane. Applicants believe the amendment to the title cures this deficiency.

Claims 1-3, 6-18 and 34 are rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement as allegedly failing to specify the intermediate component of the anti-throbogenic material. Applicants respectfully direct the Examiner to page 9, lines 6-9 and page 10, line 14 through page 12, line 9, where the specification describes embodiments of the intermediate component, e.g., the aldehyde group of the base coat (page 10, line 18), an amine group attached to the anti-thrombogenic material (page 10, line 28), amine-terminated polyethylene glycol or other chemicals such as hyaluronic acid, polyvinyl pyrrolidone (PVP) and other hydrogel type materials (page 11, lines 5-19), or aldehyde group of the cinnamaldehyde base coat (page 11, line 20 to page 12, line 9). Applicants therefore respectfully submit that these rejections are unfounded.

Claims 1-3, 6-18 and 34 are rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement for because the specification describes the term "peglated."

This term is a result of typographical error, which should be "PEGylated," a term clear to an ordinary artisan, meaning modification by binding to polyethylene glycol. Applicants believe the amendment to the specification cures this deficiency.

Claim 14 is rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement because the specification allegedly fails to provide the parameters recited therein. Applicants respectfully direct the Examiner to page 10, line 27 to page 11, line 2; page 11, lines 6-8; page 12, lines 6-8, and 18-21; page 13, lines 2-11; and Examples 4 and 5, where the specification specifically describes immobilization methods including these parameters. Applicants therefore respectfully submit that the rejection is unfounded.

Claims 1-3, 6-8, 10-18 and 34 are rejected under 35 U.S.C. 112, first paragraph, as allegedly lacking enablement for any means of polymerization. Applicants believe the amendment to the claims cures these alleged deficiencies.

Rejections under 35 U.S.C. 112, second paragraph

Claims 1-3, 6-18 and 34 are rejected under 35 U.S.C. 112, second paragraph as being indefinite. Applicants believe the amendment to the claims cures these deficiencies.

Rejections under 35 U.S.C. §102

Claims 1, 3, 7, 10, 11, 13, 15-17 and 34 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,358,557 to Wang et al. ("Wang").

Claim 1 defines a method for immobilizing an anti-thrombogenic material into a coating comprising a base coat layer posited on a surface of an implantable medical device within the mammalian body. The method comprises: (a) preparing a base coat mixture comprising a binding material, a grafting material, a photoinitiator, and a solvent; (b) applying the base coat mixture directly to the implantable medical device; (c)

polymerizing the base coat mixture to form the base coat layer on the medical device by photopolymerization; (d) applying a formulation comprising the anti-thrombogenic material to the surface of the base coat layer; and (e) immobilizing the anti-thrombogenic material directly to chemically functional groups within the base coat layer on the surface of the medical device. **The binding material includes one of polyaziridine resin compounds, polycarbodiimide resin compounds, aldehyde compounds, oxirane compounds, acetoacetoxy compounds, and isocyanate compounds**.

Wang describes a method of coating a polymeric substrate by exposing the substrate with a photo initiator, generating reactive radical sites on the surface of the substrate, contacting the substrate with a composition comprising a monomer, and grafting the monomers onto the substrate by forming covalent bonding at reactive radical sites on the substrate surface (col. 3, lines 52-64; col. 4, line 57 through col. 6, line 47). **Wang does not describe or teach a binding material**, in addition to grafting monomer materials, that includes **one of polyaziridine resin compounds, polycarbodiimide resin compounds, aldehyde compounds, oxirane compounds, acetoacetoxy compounds, and isocyanate compounds**. Therefore, claim 1 is patentably allowable over Wang under 35 U.S.C. 102(e). Claims 3, 7, 10, 11, 13 depend from claim 1 and are patentably allowable over Wang under 35 U.S.C. 102(e) for at least the same reason.

Claim 15 also defines a method comprising (a) preparing a base coat mixture comprising a binding material, a grafting material, a photoinitiator, and a solvent; (b) applying the base coat mixture directly to an implantable medical device; (c) polymerizing the base coat mixture to form the base coat layer on the medical device by photopolymerization; (d) applying a formulation comprising an anti-thrombogenic

material to the surface of the base coat layer; and (e) immobilizing the anti-thrombogenic material directly to chemically functional groups within the base coat layer on the surface of the medical device. **The binding material includes one of polyaziridine resin compounds, polycarbodiimide resin compounds, aldehyde compounds, oxirane compounds, acetoacetoxy compounds, and isocyanate compounds**. As discussed above, Wang does not describe or teach a binding material as defined in claim 15. Therefore, claim 15 is patentably allowable over Wang under 35 U.S.C. 102(e). Claims 16 and 17 depend from claim 15 and are patentably allowable over Wang under 35 U.S.C. 102(e) for at least the same reason.

Similarly, claim 34 defines a method comprising (a) preparing a base coat mixture comprising a binding material, a grafting material, a photoinitiator, and a solvent; (b) applying the base coat mixture directly to an implantable medical device; (c) polymerizing the base coat mixture to form the base coat layer on the medical device by photopolymerization; (d) applying a formulation comprising an anti-thrombogenic material to the surface of the base coat layer; and (e) immobilizing the anti-thrombogenic material directly to chemically functional groups within the base coat layer on the surface of the medical device. **The binding material includes one of polyaziridine resin compounds, polycarbodiimide resin compounds, aldehyde compounds, oxirane compounds, acetoacetoxy compounds, and isocyanate compounds**. As discussed above, Wang does not describe or teach a binding material as defined in claim 34. Therefore, claim 34 is patentably allowable over Wang under 35 U.S.C. 102(e).

Claims 1-3, and 6-12 re rejected under 35 U.S.C. 102(b) as being anticipated by WO 99/38546 (WO 38546).

Claim 1, as discussed above, defines a method for **immobilizing an anti-thrombogenic material into a coating** comprising a base coat layer posited on a surface of an implantable medical device within the mammalian body. The method requires (a) preparing a base coat mixture comprising a binding material, a grafting material, a photoinitiator, and a solvent; (b) applying the base coat mixture directly to the implantable medical device; (c) polymerizing the base coat mixture to form the base coat layer on the medical device by photopolymerization; (d) **applying a formulation comprising the anti-thrombogenic material to the surface of the base coat layer**; and (e) **immobilizing the anti-thrombogenic material directly to chemically functional groups within the base coat layer on the surface of the medical device**.

WO 38546, however, describes immobilizing a general therapeutic, diagnostic or hydrophilic agent onto a coating using a binding material. **Contrary to the Examiner's assertion, the specification and claims of WO 38546 do not describe or teach a specific therapeutic, diagnostic or hydrophilic agent. In addition, WO 38546 at page 17, lines 9-15 teaches that the hydrophilic agent is a hydrophilic polymer, which is irrelevant to an anti-thrombogenic agent as defined by claim 1 of the present invention**.

In sum, claim 1 is patentably allowable over WO 38546 under 35 U.S.C. 102(b). Claims 2, 3, and 6-12 depend from claim 1 and are patentably allowable over WO 38546 under 35 U.S.C. 102(b) for at least the same reason.

Rejections under 35 U.S.C. 103

Claims 2, 8, 9, 12, 14 and 18 have been rejected under 35 U.S.C. 103(a) as being obvious over Wang.

As discussed previously, **each of claims 2, 8, 9, 12, 14 and 18 requires a binding material that Wang fails to describe or teach**. Further, Wang does not describe or teach attaching an anti-thrombogenic material to a substrate via a binding material instead of the grafting procedure described therein. Therefore, Wang does not provide motivation for one of ordinary skill in the art to use a binding material as defined in any each of these claims to attach the anti-thrombogenic material to a substrate. Therefore, claims 2, 8, 9, 12, 14 and 18 are patentably allowable over Wang under 35 U.S.C. 103(a).

Claim 5 is rejected as being obvious over Wang in light of U.S. Patent No. 5,620,738 to Fan et al. ("Fan") under 35 U.S.C. 103(a).

Claim 6 depends from claim 1 and requires **attaching an anti-thrombogenic material to a base coat layer via a binding material includes one of polyaziridine resin compounds, polycarbodiimide resin compounds, aldehyde compounds, oxirane compounds, acetoacetoxy compounds, and isocyanate compounds**. In contrast, Fan describes using a binder polymer with aldehyde or isocyanate functional groups **to attach lubricious acrylic-based polymers to stents**. Fan does not describe or teach attaching an anti-thrombogenic material to a coating and therefore does not cure the deficiencies of Wang. Accordingly, claim 6 is patentably allowable over Wang in view of Fan under 35 U.S.C. 103(a).

CONCLUSION

Withdrawal of the rejection and allowance of the claims are respectfully requested. **If the Examiner has any suggestions or amendments to the claims to place the claims in condition for allowance, applicant would prefer a telephone call to the undersigned attorney for approval of an Examiner's amendment.** If the Examiner has any questions or concerns, the Examiner is invited to telephone the undersigned attorney at (415) 393-9885.

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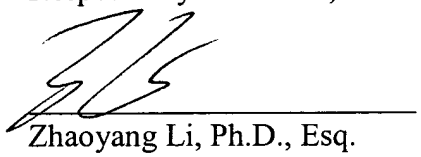
Respectfully submitted,



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